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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,816	12/21/2005	Masao Takinami	027550-177	2847

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EXAMINER
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NGUYEN, HUONG Q

ART UNIT	PAPER NUMBER
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3736

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,816	<b>Applicant(s)</b> TAKINAMI ET AL.	
	<b>Examiner</b> HELEN NGUYEN	<b>Art Unit</b> 3736	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/21/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. The preliminary amendment dated 12/12/2005 containing amendments to the specification and claims is acknowledged. Claims 1, 3-4 7-8, 10-11, and 13 are amended. Claims 14-19 are new. **Claims 1-19** remain pending and under prosecution.

#### ***Priority***

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in Application No. 10561816, filed on 12/21/2005. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### ***Information Disclosure Statement***

3. The information disclosure statement (IDS) submitted on 12/21/2005 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

#### ***Drawings***

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the spaced apart openings at opposite ends of the contact portion of **Claim 16** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

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replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency.

Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

5. **Claims 7-15** are objected to because of the following informalities:
6. Regarding **Claims 7-8**, the preamble appears to cause some confusion as to the type of claim. For example, it is suggested that said claims recite, “A method for sampling a body fluid” to clearly distinguish said claims as method claims.
7. Regarding **Claim 8**, said body fluid sampled portion on recited on p.8 lacks antecedent basis.
8. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. **Claims 16-19** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. In particular, it is unclear how the contact portion possesses spaced apart opening at opposite ends. Please see the drawing objections above. Furthermore, because there is no recitation of the location of the body relative the contact portion, it is unclear how one end of the inclined surface is located closer to the body and positioned closer to a central axis of the opening of the body than the other end of the inclined surface.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. **Claims 1-15** are rejected under 35 U.S.C. 102(a) as being anticipated by

Takinami et al (US Pub No. 20030109808).

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14. In regards to **Claim 1**, Takinami et al disclose a body fluid sampling implement used by installing a piercing needle 14 therein and allowing a body fluid to be discharged by piercing a body fluid sampled portion with said piercing needle, comprising:

a body 5 storing said piercing needle and having an opening 53 allowing said piercing needle 14 to pass therethrough, best seen in Figure 3-4;

a contact part 163 fixedly installed on said body so as to surround an outer periphery of said opening and pressed by said body fluid sampled portion, i.e. finger 200, when said body fluid sampled portion is pierced by said piercing needle, best seen in Figure 5-6,

wherein an inner surface from flange 164 of said contact part 163 has a portion tilted in such a manner that in a direction approaching said opening the tilted portion comes closer to a central axis of said opening, best seen in Figure 2, as the tilt from contact portion 163.

15. In regard to **Claims 2 and 9**, Takinami et al disclose said inner surface of said contact part 163 is in the shape of a truncated cone in side view, best seen in Figure 2.

16. In regard to **Claims 3, 10, and 15**, Takinami et al disclose said piercing needle 14 is mounted to said body fluid sampling implement as a chip 13 stored in a chip body having an opening 162 allowing said piercing needle to pass therethrough, best seen in Figure 2, and said body fluid sampled portion 200 abuts on an edge portion of said opening of said chip body when said body fluid sampled portion is pressed against said

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contact part in the condition where said chip is mounted to said body fluid sampling implement, best seen in Figure 2 and 5-6.

17. In regard to **Claims 4 and 11**, Takinami et al disclose an opening area of said opening 162 of said chip body 13 is smaller than an opening area of said opening 53 of said body 5, best seen in Figure 4.

18. In regards to **Claim 5 and 12**, Takinami et al disclose said edge portion of said opening 162 of said chip body 13 is located substantially on an extension plane of said tilted portion of said inner surface of said contact part 163, in the condition before said body fluid sampled portion is pierced with said piercing needle, best seen in Figure 4.

19. In regards to **Claim 6 and 13-14**, Takinami et al disclose the body fluid sampling implement is capable of being used in the condition where said opening of said body 5 is directed vertically upward.

20. In regard to **Claims 7 and 8**, Takinami et al disclose a body fluid sampling method carried out by use of a body fluid sampling implement comprising:

a body 5 storing a piercing needle 14 and having an opening 53 allowing said piercing needle to pass therethrough, best seen in Figure 3-4;

a contact part 163 fixedly installed on said body so as to surround an outer periphery of said opening, an inner surface from flange 164 of said contact part having a portion tilted in such a manner that in a direction approaching said opening the tilted

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portion comes closer to a center axis of said opening due to contact portion 163, best seen in Figure 2,

said method comprising: pressing a body fluid sampled portion 200 into close contact with said inner surface of said contact part 163, best seen in Figure 5;

operating said piercing needle 14 so as to pierce with said piercing needle a portion of said body fluid sampled portion which is projected into said body through said opening, best seen in Figure 6;

sampling body fluid discharged from the portion of said body fluid sampled portion that is pierced by said piercing needle, best seen in Figure 12.

21. **Claims 16-18** are rejected under 35 U.S.C. 102(b) as being anticipated by Nishikawa et al (US Pat No. 6315738).

22. In regards to **Claim 16**, Nishikawa et al disclose a body fluid sampling implement comprising:

a piercing needle 4 adapted to pierce a body fluid sampled portion to discharge body fluid from the body fluid sampled portion, the piercing needle being housed in a tube 2, best seen in Figure 2;

a body 9 adapted to receive the tube and possessing an opening 5 allowing said piercing needle to pass therethrough when said tube is received in the body, best seen in Figure 1 and 6;

a contact part around opening 31 against which is to be pressed the body fluid sampled portion to permit the piercing needle to pierce the body fluid sampled portion,



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the contact portion possessing spaced apart openings at opposite ends and an inner surface extending between the openings, at least a part of the inner surface of the contact portion being configured as an inclined surface ( $\alpha$ ), the inclined surface having opposite ends, one of the ends of the inclined surface being located closer to the body than the other end of the inclined surface, the one end of the inclined surface located closer to the body being positioned closer to a central axis of the opening than the other end of the inclined surface., best seen in Figure 4.

23. In regards to **Claim 17**, Nishikawa et al disclose the inner surface of the contact part possesses a truncated cone shape in side view, best seen in Figure 4.

24. In regards to **Claim 18**, Nishikawa et al disclose the tube 2 and the piercing needle 4 form a part of a chip, the tube being an inner tube 2 possessing an opening 22 through which the piercing needle is adapted to pass, said chip also comprising an outer tube 3 disposed at an outer periphery of the inner tube and a test paper 32 fixed to the outer tube, best seen in Figure 1, 4, and 6.

### ***Claim Rejections - 35 USC § 103***

25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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26. **Claim 19** is rejected under 35 U.S.C. 103(a) as being unpatentable over Nishikawa et al.

27. Nishikawa et al disclose the openings of the contact part possess different diameters but do not explicitly disclose a ratio of the diameter of one of the openings of the contact part to the diameter of the other opening of the contact part being in a range of 1.1 to 2.0. However, it is noted that Applicant does not appear to disclose that a particular ratio of the diameter of the openings provides an advantage, is used for a particular purpose, or solves a stated problem. Thus, the ratio is deemed not to be a critical aspect of the instant invention. Furthermore, one of ordinary skill in the art would have expected the invention of Nishikawa et al and Applicant's own invention, to perform equally as well with the openings having any ratio above 1.0, i.e. openings of different size, because any difference in size is sufficient to create the inclined surface of the instant invention. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Nishikawa et al to have the ratio of the diameter of one of the openings of the contact part to the diameter of the other opening of the contact part being in a range of 1.1 to 2.0 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Nishikawa et al.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736